



Patient Information Sheet

Clozapine (marketed as Clozaril)

This is a summary of the most important information about clozapine. For details, talk to your healthcare professional.

FDA ALERT [04/2005] – Clozapine is a type of medicine called an atypical antipsychotic. FDA has found that older patients treated with atypical antipsychotics for dementia had a higher chance for death than patients who did not take the medicine. This is not an approved use.

FDA has asked the companies that make these medicines to change their labels to include this important information.

This information reflects FDA's current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What is Clozapine?

Clozapine is a prescription medicine used to treat people with severe forms of schizophrenia that have not responded to or cannot take other treatments. Clozapine is also used to lower the risk of suicidal behavior in people with schizophrenia or schizoaffective disorder. Clozapine is not approved for use in children.

Who Should Not Take Clozapine?

You should not take clozapine if:

- You are taking other medicines that can cause the same serious bone marrow side effects as clozapine.
- You can ask your healthcare professional for a complete list of these medications.

What are The Risks?

The following are the major potential risks and side effects of clozapine therapy. However, this list is not complete.

Clozapine can cause serious problems such as:

- **Aggranulocytosis**, a potentially life-threatening reaction where the body's bone marrow does not produce enough white blood cells. Because of this risk, your healthcare professional must monitor your blood while you are taking clozapine.
- **Seizures**. The risk of seizure is increased in people who have a history of seizures or other predisposing factors. Because of this risk you should not engage in any activity where you may suddenly lose consciousness, such as operating complex machinery, driving, swimming, climbing, etc.

- **Heart problems**. Clozapine can cause a condition called myocarditis, or swelling of the heart muscle. Some of the warning signs of myocarditis are tiredness, shortness of breath, rapid breathing, fever, chest pain, and irregular heart beat. If these happen, call your healthcare professional right away.
- **Lowering of blood pressure** when you stand up. This may also lead to fainting. In rare instances, this has been associated with lung and/or heart collapse.

Clozapine and other antipsychotic medications can cause serious problems such as:

- **A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS)**. NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- **A movement problem called tardive dyskinesia (TD)**. Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes**. Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- **Other serious side effects may** include fever, blood clots in the lung, increased blood sugar, and liver disease.
- **The most common side effects** include drowsiness, increased salivation, rapid heart beat, dizziness, constipation, headache, shaking, and lightheadedness.

What Should I Tell My Healthcare Professional?

Before you start using clozapine, tell your healthcare professional if you:

- have or had heart or lung problems
- have or had seizures
- have or had blood clots
- have or had diabetes or increased blood sugar
- have or had liver disease
- have or had glaucoma
- have or had stomach problems
- have or had prostate enlargement
- are trying to become pregnant, are already pregnant, or are breast-feeding.
- drink alcohol
- smoke





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Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with clozapine, review all medications that you are taking with your health care professional, including those that you take without a prescription. You should not take clozapine if you are taking other medicines that can cause the same serious bone marrow side effects as clozapine.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- certain medicines used to treat anxiety, called benzodiazepines
- certain medicines used to clear thoughts, called psychotropic drugs
- epinephrine
- phenytoin
- rifampin
- cimetidine
- erythromycin
- carbamazepine
- fluvoxamine
- paroxetine

Avoid drinking alcohol while taking clozapine.

Is There Anything Else I Need to Know?

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with clozapine, especially when you first start taking this medicine or when the dose is increased.
- Clozapine may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how clozapine affects you.

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